



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-D-4461]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products; Study Design Recommendations for Residue Studies in Honey for Establishing Maximum Residue Levels and Withdrawal Periods; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry (GFI) #243 entitled "Studies to Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-Producing Species: Study Design Recommendations for Residue Studies in Honey for Establishing MRLs and Withdrawal Periods" (VICH GL56). This guidance has been developed for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This VICH guidance document is intended to provide study design recommendations that will facilitate the universal acceptance of the generated residue depletion data to fulfill the national/regional requirements in order to establish appropriate Maximum Residue Limits (MRLs) or other safe limits in honey following the treatment of honeybees with veterinary drug products, or to justify withdrawal periods in honey for registration or approval purposes, as applicable, when an MRL already exists.

DATES: The announcement of the guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2016-D-4461 for "Studies to Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-Producing Species: Study Design Recommendations for Residue Studies in Honey for Establishing MRLs and Withdrawal Periods" (VICH GL56). Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made

publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential."

Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Julia Oriani, Center for Veterinary Medicine (HFV-151), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-402-0788, julia.oriani@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of final GFI #243 entitled "Studies to Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-Producing Species: Study Design Recommendations for Residue Studies in Honey for Establishing MRLs and Withdrawal Periods" (VICH GL56). In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote the international harmonization of regulatory requirements. FDA has participated in efforts to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify, and then reduce, differences in technical requirements for drug development among regulatory agencies in different countries.

FDA has actively participated in the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use for several years to develop, with input from both regulatory and industry representatives, harmonized technical requirements for the registration or approval of pharmaceutical products for human use among the European Union, Japan, and the United States. The VICH is a parallel initiative for veterinary medicinal products. The VICH is concerned with developing harmonized technical requirements for the approval of veterinary medicinal products in the European Union, Japan, and the United States, and includes input from both regulatory and industry representatives.

The VICH Steering Committee is composed of member representatives from the European Commission and European Medicines Agency; International Federation for Animal Health--Europe; FDA; the U.S. Department of Agriculture; the U.S. Animal Health Institute; the Japanese Ministry of Agriculture, Forestry, and Fisheries; and the Japanese Veterinary Products Association. Six observers are eligible to participate in the VICH Steering Committee: one representative from the government of Australia/New Zealand, one representative from the

industry in Australia/New Zealand, one representative from the government of Canada, one representative from the industry in Canada, one representative from the government of South Africa, and one representative from the industry in South Africa. The World Organisation for Animal Health, the Associate Member, has one delegate. The VICH Secretariat, which coordinates the preparation of documentation, is provided by HealthforAnimals.

In the *Federal Register* of January 5, 2017 (82 FR 1342), FDA published the notice of availability for a draft guidance entitled "Studies to Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-Producing Species: Study Design Recommendations for Residue Studies in Honey for Establishing MRLs and Withdrawal Periods " (VICH GL56), giving interested persons until March 6, 2017, to comment on the draft guidance. FDA received two comments on the draft guidance, and those comments, as well as those received by other VICH member regulatory agencies, were considered as the guidance was finalized. The guidance announced in this notice finalizes the draft guidance dated January 2017. The final guidance is a product of the Metabolism and Residue Kinetics Expert Working Group of the VICH.

This VICH guidance document is intended to provide study design recommendations that will facilitate the universal acceptance of the generated residue depletion data to fulfill the national/regional requirements in order to establish appropriate MRLs or other safe limits in honey following the treatment of honeybees with veterinary drug products, or to justify withdrawal periods in honey for registration or approval purposes, as applicable, when an MRL already exists.

II. Significance of Guidance

This guidance, developed under the VICH process, is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). For example, the document has been designated "guidance" rather than "guideline." In addition, guidance documents must not include mandatory language such as "shall," "must," "require," or "requirement," unless FDA is using these words to describe a statutory or regulatory requirement.

The guidance represents the current thinking of FDA on "Studies to Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-Producing Species: Study Design Recommendations for Residue Studies in Honey for Establishing MRLs and Withdrawal Periods" (VICH GL56). It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

III. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 514 have been approved under OMB control number 0910-0032.

IV. Electronic Access

Persons with access to the internet may obtain the guidance at either <https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm> or <https://www.regulations.gov>.

Dated: November 7, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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